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- (b) substantially separating the support and bound target polynucleotide from the sample, thereby producing a separated target polynucleotide; and
- (c) amplifying <u>in vitro</u> the <u>separated</u> target polynucleotide <u>of (b)</u>.
- 4. (Amended) The method of claim 1 wherein [the target polynucleotide is amplified with a polymerase] said amplifying *in vitro* comprises amplifying said separated target polynucleotide with a polymerase.
- 5. (Amended) The method of claim 4 wherein the polymerase is a DNA polymerase, an RNA polymerase, or a transcriptase [or $Q\beta$ replicase].
- 6. (Amended) The method of claim 4 wherein the <u>separated</u> target polynucleotide is a DNA polynucleotide and the polymerase is a DNA polymerase.
- 7. (Twice Amended) A method for detecting a target polynucleotide contained in a sample comprising the steps of:
- (a) contacting the sample with a first support which binds to the target polynucleotide;
- (b) substantially separating the first support and bound target polynucleotide from the sample, thereby producing a separated target polynucleotide;
- (c) amplifying <u>in vitro</u> the <u>separated</u> target polynucleotide <u>of (b)</u>, thereby producing an amplified <u>target polynucleotide</u>; and
- (d) detecting the presence of the amplified target polynucleotide of (c) as indicative of the presence of the target polynucleotide in said sample.
- 10. (Amended) The method of claim 7 wherein [the target polynucleotide is amplified with a polymerase] said amplifying *in vitro* comprises amplifying said separated target polynucleotide with a polymerase.
- 11. (Amended) The method of claim 10 wherein the polymerase is a DNA polymerase, an RNA polymerase, \underline{or} a transcriptase [or Q β replicase].
- 12. (Amended) The method of claim 11 wherein the <u>separated</u> target polynucleotide is a DNA polynucleotide and the polymerase is a DNA polymerase.
- 13. (Amended) The method of claim 7 wherein the amplified target polynucleotide is

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- 14. (Amended) The method of claim 7 wherein the amplified target polynucleotide is contacted with a labeled probe, and the presence of the target polynucleotide in the sample is indicated by detection of said labeled probe.
- 16. (Amended) The method of claim 15 wherein the [amplified target polynucleotide is contacted with] second support includes a labeled probe, and the presence of the target polynucleotide in the sample is indicated by detection of said labeled probe.
- 17. (Amended) The method of claim 16 wherein [the target polynucleotide is amplified with a polymerase] said amplifying *in vitro* comprises amplifying said separated target polynucleotide with a polymerase.
- 18. (Amended) The method of claim 17 wherein the <u>separated</u> target polynucleotide is a DNA polynucleotide and the polymerase is a DNA polymerase.
- 19. (Three-times Amended) A method for detecting a target polynucleotide contained in a sample comprising the steps of:
- (a) contacting the sample with a first support which binds to the target polynucleotide;
- (b) substantially separating the first support and bound target polynucleotide from the sample, thereby producing a separated target polynucleotide;
- (c) amplifying <u>in vitro</u> the [sample] <u>separated target polynucleotide of (b)</u> with a DNA polymerase, thereby producing an amplified target polynucleotide;
- (d) contacting the amplified target polynucleotide of (c) with a second support which binds to the amplified target polynucleotide and also with a labeled probe which binds to the amplified target polynucleotide; and
- (e) detecting the presence of [the amplified target polynucleotide] the labeled probe as indicative of the presence of the target polynucleotide in said sample.
- 27. (Twice Amended) A method for amplifying a target polynucleotide contained in a sample medium comprising the steps of:

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- (a) contacting the sample medium with <u>a</u> reagent comprising a first nucleic acid probe which binds to the target <u>polynucleotide</u> to form a probe-target complex;
- (b) contacting the sample medium with a support which binds to the first nucleic acid probe of the probe-target complex;
- (c) substantially separating the support and bound probe-target complex from the sample medium;
- (d) contacting the support and bound probe-target complex with a second medium;
- (e) releasing the probe-target complex into the second medium;
- (f) substantially separating the support from the second medium; and
- (g) amplifying <u>in vitro</u> the target polynucleotide <u>in the probe-target complex present in the second medium.</u>
- 28. (Twice Amended) A method for detecting a target polynucleotide contained in a sample medium comprising the steps of:
- (a) contacting the sample medium with <u>a</u> reagent comprising a first nucleic acid probe which binds to the target <u>polynucleotide</u> to form a probe-target complex;
- (b) contacting the sample medium with a support which binds to the first nucleic acid probe of the probe-target complex;
- (c) substantially separating the support and bound probe-target complex from the sample medium;
- (d) contacting the support and bound probe-target complex with a second medium;
- (e) releasing the probe-target complex into the second medium;
- (f) substantially separating the support from the second medium;
- (g) amplifying <u>in vitro</u> the target polynucleotide <u>in the probe-target complex present in the second medium;</u> and
- (h) detecting the presence of the target polynucleotide in the second medium as indicative of the presence of the target polynucleotide in said sample.
- 29. (Amended) The method of detecting a target polynucleotide of claim 28 wherein [the

target polynucleotide is amplified with a polymerase] <u>said amplifying in vitro comprises</u> amplifying said target polynucleotide with a polymerase.

- 30. (Amended) The method for detecting a target polynucleotide of claim 29 wherein the polymerase is a DNA polymerase, an RNA polymerase, or a transcriptase[, or $Q\beta$ replicase].
- 32. (Amended) The method for amplifying a target polynucleotide of claim 27 wherein [the target polynucleotide is amplified with a polymerase] said amplifying in vitro comprises amplifying said target polynucleotide with a polymerase.
- 34. (Twice Amended) A method for amplifying a target polynucleotide contained in a sample medium comprising the steps of:
- (a) contacting the sample medium with a support and a probe which binds to the target polynucleotide and the support;
- (b) substantially separating the support and bound probe and target polynucleotide from the sample medium;
- (c) contacting the support and bound probe and target polynucleotide with a second medium;
- (d) releasing the target polynucleotide $\underline{of(c)}$ into the second medium;
- (e) substantially separating the support and bound probe from the second medium; and
- (f) amplifying *in vitro* the target polynucleotide <u>present in the second medium</u>.
- 35. (Twice Amended) The method for amplifying a target polynucleotide of claim 34 wherein [the target polynucleotide is amplified with a polymerase] <u>said amplifying in vitro</u> comprises amplifying said target polynucleotide with a polymerase.
- 36. (Amended) The method for amplifying a target polynucleotide of claim 35 wherein the polymerase is a DNA polymerase, an RNA polymerase, or a transcriptase [or $Q\beta$ replicase].
- 38. (Twice Amended) A method for detecting a target polynucleotide contained in a sample medium comprising the steps of:
- (a) contacting the sample medium with a support and probe which binds to the target polynucleotide and the support;
- (b) substantially separating the support and bound probe and target polynucleotide from the

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 sample medium;

- (c) contacting the support and bound probe and target polynucleotide with a second medium;
- (d) releasing the target polynucleotide of (c) into the second medium;
- (e) substantially separating the support and bound probe [form] from the second medium;
- (f) amplifying <u>in vitro</u> the target polynucleotide <u>present in the second medium, thereby producing</u> an amplified target polynucleotide; and
- (g) detecting the presence of the amplified target polynucleotide in the second medium as indicative of the presence of the target polynucleotide in said sample.
- 39. (Amended) The method for detecting a target polynucleotide of claim 38 wherein [the target polynucleotide is amplified with a polymerase] <u>said amplifying in vitro comprises</u> <u>amplifying said target polynucleotide with a polymerase</u>.

Of the claims 41-59 introduced in the Preliminary Amendment of March 8, 2000, please cancel claims 41, 47, and 53-59 without prejudice (if they have not yet been canceled). Please amend claims 42-46 and 48-52 as follows: (the attached Appendix I identifies the changes from the claims as introduced):

The amplification method of claim 1 wherein said amplifying in vitro is linear or exponential.

The amplification method of claim 2 wherein said amplifying in vitro is exponential.

The amplification method of claim 1 wherein said amplifying in vitro comprises amplifying said separated target polynucleotide with at least one oligonucleotide primer.

45. The amplification method of claim 44 wherein said amplifying in vitro is linear or exponential.

The amplification method of claim 1 wherein said amplifying in vitro comprises amplifying said separated target polynucleotide with more than one polymerase.

The detection method of claim 7 wherein said amplifying in vitro is linear or exponential.

The detection method of claim 48 wherein said amplifying in vitro is exponential.

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The detection method of claim 7 wherein said amplifying in vitro comprises amplifying said separated target polynucleotide with at least one oligonucleotide primer. The detection method of claim wherein said amplifying in vitro is linear or exponential. The detection method of claim 7 wherein said amplifying in vitro comprises amplifying said separated target polynucleotide with more than one polymerase. Please cancel claims 60-63 added by the Preliminary Amendment of July 16, 2001 (if they are not already canceled). Of the claims 64-82 added in the Amendment of March 8, 2002, please cancel claims 68, 69, and 76-82 without prejudice. Please amend claims 64-67 and 71-72 as follows (the attached Appendix I identifies the changes from the claims as introduced): The method of claim 1 wherein said amplifying in vitro comprises amplifying said separated target polynucleotide non-specifically. The method of claim 1 wherein said amplifying in vitro comprises amplifying said separated target polynucleotide specifically. The method of claim 7 wherein said amplifying in vitro comprises amplifying said separated target polynucleotide non-specifically. The method of claim 7 wherein said amplifying in vitro comprises amplifying said separated target polynucleotide specifically. The method of claim 70 wherein said amplifying in vitro comprises amplifying said separated target polynucleotide non-specifically. The method of claim 70 wherein said amplifying in vitro comprises amplifying said separated target polynucleotide specifically. 1300 I Street, NW Vashington, DC 20005 202.408.4000 Fax 202.408.4400 www.finnegan.com

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1300 I Street, NW Washington, DC 20005 202.408.4000 Fax 202.408.4400 www.finnegan.com Please add new claims 83-86 as follows:

- The method of claim 1 wherein said amplifying in vitro comprises amplifying said separated target polynucleotide with specially tailored primers.
- 84. The method of claim 7 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide with specially tailored primers.
- 85. The method of claim 70 wherein said amplifying in vitro comprises amplifying said separated target polynucleotide with specially tailored primers.
- 26. The method of claim & wherein the sample is a clinical sample.

REMARKS

The Patent Owner and its representatives wish to express their appreciation to each of the PTO representatives that has participated in the examination of this application. Specifically, the Patent Owner thanks Supervisory Primary Examiner Gary Jones, Special Programs Examiner Julie Burke, Primary Examiner Carla Myers, Primary Examiner Lisa Arthur, and particularly, Examiner Dianna Johannsen.

The amendments presented here reflect the draft proposed amendment of March 28, 2002, as discussed and modified during the interview of April 2, 2002, and as reflected in the Interview Summary forwarded by facsimile on April 3, 2002. After these amendments, claims 1-19, 27-40, 42-46, 48-52, 64-67, 70-75, and 83-86 will be pending. As discussed with the Examiner on Friday, April 11, 2002, the prior request to cancel claim 44 in the March 8th Amendment has not yet been entered so that claim is currently pending and has been amended in this Supplemental Amendment. To assist the Office, a clean copy of these pending claims is attached in Appendix II.

As noted during the Interview, the submission of additional claim amendments necessitates the filing of a supplemental oath/declaration to satisfy the requirements of 35 U.S.C. 251. Accordingly, the Patent Owner is submitting herewith a second supplemental reissue declaration by its representative Norval Galloway that states that: